EXPANDABLE BLOOD PUMP AND RELATED METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is an International Patent Application of and claims the benefit of priority from commonly owned and co-pending U.S. Provisional Patent Applications Serial Nos. 60/388,136 (filed June 11, 2002), the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to a system for assisting the heart and, more particularly, to a pumping system and related method for supplementing the circulation of blood through the patient using a minimally invasive procedure.

II. Description of Related Art

Over the years, various types of percutaneously introduced blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Such blood pumps may be positioned within the heart of the patient (so-called "intracardiac blood pumps") or may be positioned within the associated vasculature of the patient (so-called "intravascular blood pumps"). Such percutaneously introduced blood pumps have experienced proliferated growth and attention in that they are capable of supplementing or replacing the circulation of blood through the patient using minimally invasive techniques (eliminating the trauma of an open procedure), and minimize the need to route the blood outside the patient (reducing trauma to the blood).

Although generally advantageous for these reasons, among others, the percutaneously introduced blood pumps of the prior art nonetheless suffer from various drawbacks. One such drawback involves the tradeoff between the size of the pump and the ability to deliver blood at sufficient rates. For example, the Hemopump is an axial flow blood pump which meets the criteria for blood flow (approximately 3 liters per minute) but it is too large (14 to 22 French) for easy insertion by a cardiologist. Although smaller versions of the Hemopump could be built, physics limits the flow because as the

pump becomes smaller, the inlet area decreases. Losses in the pump increase in a rapid, non-linear manner as the inlet area decreases. To compensate for these rapidly increasing losses, the rotor speed must be increased exponentially. Although adequate flow may be achieved, hemolysis increases to unacceptable levels.

Thus the engineer faces theoretical and technical difficulties to make a traditional propeller pump or centrifugal pump with the diameter less than 4.0 mm and a flow of at least 3 liters per minute. One way to circumvent the physical limitations imposed by a decreasing inlet area is to make the pump expandable. In this way, inlet losses and shaft speed can be minimized since large areas can be achieved after the pump is inserted. Cable driven axial flow blood pumps have been described which use a hinged propeller that deploys after insertion into the arterial system. However, the work delivered by the hinged rotor was not constrained by a housing to create an effective blood pumping from inlet to outlet. Rather, these pumps have created a significant blood re-circulation without much effective blood pumping.

The present invention is directed at eliminating, or at least reducing the effects of, the above-described problems with the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the limitations of the prior art by providing a pumping system capable of being expanded from a first state of generally reduced dimension to a second state of generally increased dimension. The blood pump of the present invention may be advantageously introduced into the patient (and onward to the pumping site) while in the first state and thereafter operated (automatically or manually) into the second state for use in pumping blood to augment or replace the pumping capacity of the patient's heart. More specifically, this is accomplished by equipping the blood pump of the present invention with a pump housing with an internally disposed rotor, wherein each of the pump housing and rotor are capable of being expanded from a first state of generally reduced dimension to a second state of generally increased dimension. In this fashion, the blood pump of the present invention may be percutaneously introduced through a much smaller opening than prior art blood pumps without sacrificing the degree to which it can achieve high blood flow rates.

The present invention also achieves a variety of objectives, several of which are set forth below by way of example only. One such objective is to achieve the benefits of an expandable pump by using a centrifugal rotor in association with a housing designed to channel blood away from the rotor in order to increase the pump efficiency.

It is another object of the present invention to provide a blood pump, which is expandable to allow device insertion through a peripheral vessel without the need of a surgical access.

A further object of the invention is to provide a blood pump with a small diameter that is small enough to permit percutaneous insertion of the pump into a patient's blood vessel.

It is another object of the present invention to provide a blood pump, which is expandable to allow the increased flow capacity of a small diameter pump.

In the illustrative embodiment of the present invention, the blood pump head has a conical housing portion. The conical housing portion defines a blood inlet port, a cavity for rotor deployment, and an outflow port, which is in communication with an outflow cannula.

In the illustrative embodiment, the housing is supported by the deploying catheter to maintain a cylindrical shape and assure the separation between the rotor and housing.

In one embodiment, the impeller comprises a second expandable catheter, wherein upon expansion forms the blade of the impeller.

In another embodiment, the impeller comprises multiple discs that are inserted in the folded position and naturally deploy to a circular shape when are not constrained.

In another embodiment, the impeller is formed by a slit tube that deforms to form a conical shape when the distal and proximal ends are pulled toward each other. A soft thin sheath covering the slit tube will deform to form the outer skin of the conical shape. In essence, the outer sheath could deform to form ridges simulating an impeller shape.

In the illustrative embodiment, the impeller shaft is magnetically coupled to the motor. In another embodiment, the motor is coupled to the impeller shaft via a flexible shaft.

In one embodiment, the blood pump has an outer dimension that is small enough to permit percutaneous insertion of the pump into a patient's blood vessel. A collapsible polymeric outflow tube is provided and is coupled to the blood flow outlet of the pump and is adapted for directing the blood from the left ventricle of the patient to the aorta through the aortic valve.

In accordance with the present invention, a method is provided for pumping blood. The method comprises the steps of providing an expandable pump head having an elongated housing portion defining a blood inlet port on a surface thereof and a blood outlet port on a surface thereof; providing an impeller within said housing portion for providing centrifugal or axial flow of the blood from the inlet port to the outlet port; and driving the expandable pump head with a motor to rotate the impeller and accelerate the blood from the inlet port within the housing portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a is a schematic illustration of the frontal view of the pump head in the expanded status according to the present invention;

FIG. 1b is a schematic illustration of the side view of the pump head in the expanded status;

FIG 2a is a schematic illustration of the frontal view of the pump head in the collapsed status;

FIG. 2b 1a is a schematic illustration of the side view of the pump head in the collapsed status;

FIG. 3a is a longitudinal cross-sectional view of the pump head in the expanded status;

FIG. 3b is a longitudinal cross-sectional view of the pump head in the collapsed status;

FIG. 3c is a schematic illustration of the frontal view of the pump head in the expanded status;

FIG. 3d is a schematic illustration of the frontal view of the pump head in the collapsed status;

FIG. 4a is a longitudinal cross-sectional view of the pump head in the expanded status;

FIG. 4b is a radial cross-sectional view along line A—A of FIG 4a showing the pump head in the expanded status;

FIG 5a is an enlarged view of the circled section of the longitudinal cross-sectional view of the pump head in the expanded status with details to blood seal and pump bearings;

FIG 5b is an enlarged view of the circled section of the longitudinal cross-sectional view of the pump head in the collapsed status with details to blood seal and pump bearings;

FIG 6 is a schematic illustration of the side view of the outflow cannula in the expanded status;

FIG 7a is a schematic illustration of the frontal view of an alternative embodiment of the pump rotor in the collapsed status according to the present invention;

FIG 7b is a schematic illustration of the frontal view of the alternative embodiment shown in FIG 7a of the pump rotor in the expanded status according to the present invention;

FIG. 8a is a longitudinal cross-sectional view an alternative embodiment of the pump head and outflow cannula in the expanded status according to the present invention;

FIG 8b is a schematic illustration of the frontal view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the expanded status;

FIG. 8c is a longitudinal cross-sectional view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the collapsed status according to the present invention;

FIG 8d is a schematic illustration of the frontal view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the collapsed status according to the present invention;

FIG 9 is a schematic illustration of the side view of an alternative embodiment of the pump rotor in the expanded status according to the present invention;

FIG 10 is a longitudinal cross-sectional view an alternative embodiment of the pump head and outflow cannula in the expanded status according to the present invention;

FIG 11a is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the collapsed status according to the present invention;

FIG 11b is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 11a of the pump rotor in the expanded status;

FIG 11c is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the collapsed status;

FIG 11d is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 11c of the pump rotor in the expanded status;

FIG 12a is schematic view of an alternative embodiment of the pump rotor in the expanded status according to the present invention;

FIG 12b is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 12a of the pump rotor in the collapsed status;

FIG 12c is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the expanded status;

FIG 12d is a perspective view, partially in section, of the pump rotor shown in FIG 12c rotor in the expanded status;

FIG. 13a is a schematic illustration of the frontal view of an alternative embodiment of the pump head in the expanded status according to the present invention;

FIG. 13b is a is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 13a of the pump head in the expanded status;

FIG. 13c is a schematic illustration of the frontal view of the alternative embodiment shown in FIG 13a of the pump head in the expanded status with an outflow cannula in place;

FIG. 13c is a longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 13a of the pump rotor in the expanded status;

FIG 14a is a perspective view, partially in section, of an alternative embodiment of the pump head in the expanded status according to the present invention;

FIG 14b is a perspective view of the alternative embodiment of the pump head shown in FIG 14 a in the expanded status;

FIG 14b is a perspective view of the alternative embodiment of the pump head shown in FIG 14 a in the collapsed status;